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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,338	05/15/2006	Krishnareddy Guddadarangavvnahally	52956.1.1	1023

22859 7590 10/08/2008
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EXAMINER

CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
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1655

MAIL DATE	DELIVERY MODE
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10/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,338	Applicant(s) GUDDADARANGAVVNAHALLY ET AL.	
	Examiner CATHERYNE CHEN	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/6/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Currently, Claims 1-14 are pending. Claims 1-8 are examined on the merits.

Election/Restrictions

Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on Aug. 6, 2008.

Applicant's election with traverse of Group I (Claims 1-8), the species *Bacillus cereus*, in the reply filed on Aug. 6, 2008 is acknowledged. The traversal is on the ground(s) that there is unity of invention. This is not found persuasive because the composition can be made in a different manner, such as mixed together in a different manner. Here, the *cinnamomum zeylanicum* can be extracted with ethanol (see Kamath et al., 2003, *Phytotherapy Research*, 17, 970-972). Thus, there is no special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims are “use” claims, which is not in compliance with U.S. practice.

Claims 5-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are indefinite because it is not clear if Applicant is claiming a method or a composition. For the sake of examination, these claims will be considered as composition claims.

Claim 1 contain the terms “4-6% moisture,” “greenish white,” and “mild salty flavor” that are indefinite. The term “4-6% moisture” is indefinite because the one does not know what the percentage of moisture is being directed. Is it to

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the whole composition's moisture content or just the fruit's moisture content?

The term "greenish white" is indefinite because how green is green and how white is white? Is it more green or more white? Therefore, a "greenish white" shade would be indefinite. The term "mild salty flavor" is indefinite because how mild is mild and how salty is salty. What is the standard for determining whether it is "mildly salty" in flavor?

Claims 5-8 provide for the use of a bioactive fraction as an antibacterial agent, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Agnihotri et al. (1996, Indian J. Experimental Biology, 34, 712-715) and as evidenced by Tuninst

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(<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>).

Agnihotri et al. teaches cinnamomum zeylanium extracted with hexane and tested for antibacterial properties using gram positive and gram negative bacteria (Abstract). The whole plant of cinnamomum zeylanium, including the fruit is extracted with hexane. Fruit can be unripe or ripe. Unripe fruit would have the greenish-white color fruit, fruit is green when young (see <http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>, page 10, Plant identification characters). As evidenced by Tuninst, the relative color of greenish white, 4-6% moisture, and mild salty flavor of Cinnamomum zeylanium young fruit would inherently have the claimed color, flavor, and moisture content. Color and flavor are relative terms and can be opinions differing from person to person. Further, the limitation 4-6 % moisture is meaningless since it is not relative to anything, the whole composition ? 4-6 % of water, relative to the whole composition or just the fraction, the limitation is confusing and meaningless. In addition, as the claims are directed to a composition, the composition would inherently have antibacterial activity against Bacillus cereus in the range of 200-500 ppm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaprakasha et al. (1997, Flavour and Fragrance Journal, 12, 331-333) and Tuninst (<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>).

Jayaprakasha et al. teaches fruits of *Cinnamomum zeylanicum* were used for hydrodistillation (Experimental, Plant material and hydrodistillation). However, it does not teach 4-6% moisture, greenish white color, and mild salty flavor.

The ripe fruit of *Cinnamomum zeylanicum* is dark purple (see Jayaprakasha et al., Experimental, Plant Material). Therefore, the greenish white color fruit is the unripe fruit of *Cinnamomum zeylanicum*. Unripe fruit would have the greenish-white color fruit, fruit is green when young (see <http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>, page 10, Plant identification characters). As evidenced by Tuninst,

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the relative color of greenish white, 4-6% moisture, and mild salty flavor of *Cinnamomum zeylanium* young fruit would inherently have the claimed color, flavor, and moisture content. In addition, as the claims are directed to a composition, the composition would intrinsically have antibacterial activity against *Bacillus cereus* in the range of 200-500 ppm.

Unripe fruit have more chemically active ingredients because, with fruit maturation, many chemicals become inactive. Thus, an artisan of ordinary skill would reasonably expect that using unripe fruit of *Cinnamomum zeylanicum* could be used as the types starting material taught by the reference. This reasonable expectation of success would motivate the artisan to use unripe fruit in the reference composition. Thus, using unripe is considered an obvious modification of the references.

Claims 1-2, 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaprakasha et al. (1997, *Flavour and Fragrance Journal*, 12, 331-333) and Tuninst (<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>) as applied to claims 1, 5 above, and further in view of Poole et al. (1994, *Analyst*, 119, 113-120).

Jayaprakasha et al. teaches fruits of *Cinnamomum zeylanicum* were used for hydrodistillation (Experimental, Plant material and hydrodistillation). However, it does not teach 4-6% moisture, greenish white color, and mild salty flavor.

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The ripe fruit of *Cinnamomum zeylanicum* is dark purple (see Jayaprakasha et al., Experimental, Plant Material). Therefore, the greenish white color fruit is the unripe fruit of *Cinnamomum zeylanicum*. Unripe fruit would have the greenish-white color fruit, fruit is green when young (see <http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>, page 10, Plant identification characters). As evidenced by Tuninst, the relative color of greenish white, 4-6% moisture, and mild salty flavor of *Cinnamomum zeylanium* young fruit would intrinsically have the claimed color, flavor, and moisture content. In addition, as the claims are directed to a composition, the composition would inherently have antibacterial activity against *Bacillus cereus* in the range of 200-500 ppm.

However, it does not teach 4-6% moisture, greenish white color, and mild salty flavor, hexane.

The ripe fruit of *Cinnamomum zeylanicum* is dark purple (see Jayaprakasha et al., Experimental, Plant Material). Therefore, the greenish white color fruit is the unripe fruit of *Cinnamomum zeylanicum*. Unripe fruit have more chemically active ingredients because, with fruit maturation, many chemicals become inactive. Thus, an artisan of ordinary skill would reasonably expect that using unripe fruit of *Cinnamomum zeylanicum* could be used as the types starting material taught by the reference. This reasonable expectation of success would motivate the artisan to use unripe fruit in the reference composition. Thus, using unripe is considered an obvious modification of the references.

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Poole et al. teaches cinnamon has numerous uses in the food, pharmaceutical and cosmetic industries (page 113, left column, first paragraph), where the source of cinnamon is from *Cinnamomum zeylanicum* (page 113, right column, first paragraph). The components in *Cinnamomum* are cinnamaldehyde, cinnamyl alcohol, cinnamyl acetate, eugenol, cinnamic acid and 2-methoxycinnamaldehyde (page 114, left column, lines 15-18). Separation of cinnamon extract were performed on silica-gel layers with hexane-triethylamine, hexane-chloroform (page 115, Thin-layer Chromatography).

Hexane is used to extract compounds from *Cinnamomum zeylanicum* and unripe fruits of *Cinnamomum zeylanicum* can be used to extract compounds. Thus, an artisan of ordinary skill would reasonably expect that hexane could be used as the types solvent to extract fruits of *Cinnamomum zeylanicum* taught by the references. This reasonable expectation of success would motivate the artisan to use hexane in the reference composition. Thus, using hexane is considered an obvious modification of the references.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jayaprakasha et al. (1997, Flavour and Fragrance Journal, 12, 331-333), and Tuninst (<http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>) and Poole et al. (1994, Analyst, 119, 113-120) as applied to claims 1-2, 5-6 above, and further in view of Valero et al. (2003, International Journal of Food Microbiology, 85, 73-81).

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Jayaprakasha et al. teaches fruits of *Cinnamomum zeylanicum* were used for hydrodistillation (Experimental, Plant material and Isolation of Volatile Components). The ripe fruit of *Cinnamomum zeylanicum* is dark purple (see Jayaprakasha et al., Experimental, Plant Material). Therefore, the greenish white color fruit is the unripe fruit of *Cinnamomum zeylanicum*. Unripe fruit would have the greenish-white color fruit, fruit is green when young (see <http://www.tuninst.net/MyanMedPlants/TIL/famL/Lauraceae.htm#Cinnamomum-zeylanicum>, page 10, Plant identification characters). As evidenced by Tuninst, the relative color of greenish white, 4-6% moisture, and mild salty flavor of *Cinnamomum zeylanium* young fruit would inherently have the claimed color, flavor, and moisture content. In addition, as the claims are directed to a composition, the composition would intrinsically have antibacterial activity against *Bacillus cereus* in the range of 200-500 ppm.

However, it does not teach 4-6% moisture, greenish white color, and mild salty flavor, hexane, and *Bacillus cereus*.

The ripe fruit of *Cinnamomum zeylanicum* is dark purple (see Jayaprakasha et al., Experimental, Plant Material). Therefore, the greenish white color fruit is the unripe fruit of *Cinnamomum zeylanicum*. Unripe fruit have more chemically active ingredients because, with fruit maturation, many chemicals become inactive. Thus, an artisan of ordinary skill would reasonably expect that using unripe fruit of *Cinnamomum zeylanicum* could be used as the types starting material taught by the reference. This reasonable expectation of success would motivate the artisan to use unripe fruit in the reference

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composition. Thus, using unripe is considered an obvious modification of the references.

Poole et al. teaches cinnamon has numerous uses in the food, pharmaceutical and cosmetic industries (page 113, left column, first paragraph), where the source of cinnamon is from *Cinnamomum zeylanicum* (page 113, right column, first paragraph). The components in *Cinnamomum* are cinnamaldehyde, cinnamyl alcohol, cinnamyl acetate, eugenol, cinnamic acid and 2-methoxycinnamaldehyde (page 114, left column, lines 15-18). Separation of cinnamon extract were performed on silica-gel layers with hexane-triethylamine, hexane-chloroform (page 115, Thin-layer Chromatography).

Valero et al. teaches major antimicrobial components of spices and their essential oils are cinnamic aldehyde and eugenol in cinnamon (Introduction, right column). Antimicrobial activity tested against *B. cereus* strain INRA L2104 (page 74, left column, second paragraph). The growth inhibition of *B. cereus* spores was achieved by using 25 microliter of essential oil of cinnamon to every 100 mL of carrot broth (page 77, right column, first paragraph) and at concentrations from 5, 10, 25, 100, 200 microliter/100 mL (page 75, Table I).

Hexane is used to extract compounds from *Cinnamomum zeylanicum* and unripe fruits of *Cinnamomum zeylanicum* can be used to extract compounds. Thus, an artisan of ordinary skill would reasonably expect that hexane could be used as the types solvent to extract fruits of *Cinnamomum zeylanicum* taught by the references. This reasonable expectation of success would motivate the

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artisan to use hexane in the reference composition. Thus, using hexane is considered an obvious modification of the references.

The extracts intrinsically contain cinnamic aldehyde and eugenol in cinnamon and these compounds are found to have antimicrobial activities against *B. cereus* (Valero et al., page 74, left column, second paragraph). Therefore, the hexane extracts from *Cinnamomum zeylanicum* fruit would have antimicrobial activities.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for killing bacteria at 200-500 ppm. However, the reference Valero et al. does teach the composition for killing bacteria at different concentrations (see Table I). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

Primary Examiner, Art Unit 1655